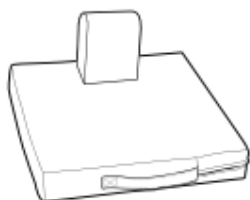


PRIMA FORM



PRIMA PLOT



KALLI HR
KALLI VISCO



ISKIO BM
ISKIO VISCO



KALLI DOS HR
KALLI DOS VISCO



Technical Manual

TABLE OF CONTENTS

TECHNICAL CHARACTERISTICS OF THE DEVICE	- 3 -
COMPATIBLES ACCESSORIES.....	- 4 -
PRECAUTIONS FOR USE/ WARNINGS.....	- 4 -
PREVENTIVE MAINTENANCE.....	- 5 -
CARE AND DISINFECTION	- 5 -
Cleaning the cover	- 5 -
Caution.....	- 6 -
DISPOSAL	- 6 -

TECHNICAL CHARACTERISTICS OF THE DEVICE

Technical characteristics:

Technical data (PRIMA PLOT)	
Viscoelastic foam	Polyurethane 80 kg/m ³ – fire classification M4
High Resilience foam	Polyurethane 40 kg/m ³ – fire classification M4
PHARMATEX cover	60% polyurethane, 40% polyester, weight 120 g/m ² – fire classification CRIB 5
Anti-slip	57% polyurethane, 43% polyester – fire classification CRIB 5
Fire resistance test	EN 597-1 & EN 597-2
Technical data (PRIMA FORM & KALLI VISCO)	
Viscoelastic foam	Polyurethane 80 kg/m ³ – fire classification M4
PHARMATEX cover	60% polyurethane, 40% polyester, weight 120 g/m ² – fire classification CRIB 5
Anti-slip	57% polyurethane, 43% polyester – fire classification CRIB 5
Fire resistance test	EN 597-1 & EN 597-2
Technical data (KALLI HR)	
High Resilience foam	Polyurethane 37 kg/m ³ – fire classification M4
JERSEY cover	100% cotton
PHARMATEX cover	60% polyurethane, 40% polyester, weight 120 g/m ² – fire classification CRIB 5
Anti-slip	57% polyurethane, 43% polyester – fire classification CRIB 5
Fire resistance test	EN 597-1 & EN 597-2
Technical data (ISKIO BM)	
Viscoelastic foam	Polyurethane 80 kg/m ³ – fire classification M4
High Resilience foam	Polyurethane 37 kg/m ³ – fire classification M4
PHARMATEX cover	60% polyurethane, 40% polyester, weight 120 g/m ² – fire classification CRIB 5
3D mesh	100% polyester – 100% polyurethane laminated film
Anti-slip	57% polyurethane, 43% polyester – fire classification CRIB 5
Fire resistance test	EN 597-1 & EN 597-2
Technical data (ISKIO VISCO)	
Viscoelastic foam	Polyurethane 80 kg/m ³ – fire classification M4
PHARMATEX cover	60% polyurethane, 40% polyester, weight 120 g/m ² – fire classification CRIB 5
3D mesh	100% polyester – 100% polyurethane laminated film
Anti-slip	57% polyurethane, 43% polyester – fire classification CRIB 5
Fire resistance test	EN 597-1 & EN 597-2
Technical data (KALLI DOS VISCO)	
Viscoelastic foam	Polyurethane 80 kg/m ³ – fire classification M4
PHARMATEX cover	60% polyurethane, 40% polyester, weight 120 g/m ²
Technical data (KALLI DOS HR)	
High Resilience foam	Polyurethane 37 kg/m ³ – fire classification M4
JERSEY cover	100% cotton

PHARMATEX cover	60% polyurethane, 40% polyester, weight 120 g/m ²
Anti-slip	57% polyurethane, 43% polyester – fire classification CRIB 5

Maximum pressure before aging at maximum weight (100 kg), for PRIMA FORM and PRIMA PLOT:

- Buttocks: 172 g/cm² (126 mmHg).

Maximum pressure before aging at maximum weight (130 kg), for KALLI VISCO:

- Buttocks: 169 g/cm² (124 mmHg).

Maximum pressure before aging at maximum weight (160 kg), for ISKIO BM:

- Buttocks: 141 g/cm² (104 mmHg).

Maximum pressure before aging at maximum weight (150 kg), for ISKIO VISCO:

- Buttocks: 142 g/cm² (104 mmHg).

The viscoelastic foam cushions meet the requirements of the protocol of the Commission for the Evaluation of Products and Services relating to cushions, mattresses, and mattress toppers to help prevent pressure sores according to the opinion of 22 December 2009.

FCBA technical conformity certificates n°19-003 (PRIMA FORM) of 26 November 2019, n°19-010 (PRIMA PLOT) of 6 December 2019, n°19-004 (KALLI VISCO) of 3rd October 2019, n°14-012 (ISKIO VISCO) of 26 June 2014, and n°19-005 (ISKIO BM) of 3 October 2019.

COMPATIBLES PROTECTIVE ACCESSORIES



Only protective accessories (e.g., PHARMATEX/JERSEY, or 3D mesh covers) distributed by WINNCARE France guarantee compatibility with our products. Incompatible accessories may create hazards.

PRECAUTIONS FOR USE/ WARNINGS

Precautions for use are as follows:

- Bone and/or muscle and/or skin trauma in the pelvic region and thigh which has not been stabilised and which is in contact with the support.
- Sitting instability.
- First days following surgery for a pressure ulcer/injury (skin graft or flap).
- Also verify the condition of the exposed part of the skin each time that care is provided.
- Fractures of the pelvis or spine.

Warning is as follow:

- (Re)assess the risks of patient entrapment in the non-mobile parts of the wheelchair fitted with the therapy cushion.

Measures required:

- A cushion must be installed on a wheelchair seat that is in good condition.
- Ensure that the dimensions of the cushion are compatible with the seat of the wheelchair. The device must be used with its original protection.

- Check the position of the pelvis, the spine, the head, the height of the armrests and the length of the leg and footrests after the patient has been placed on the cushion.
- A cushion alone is not enough to prevent pressure ulcers/injuries; other preventive measures are also required:
 - o Change position at least once every 2 hours,
 - o Maintain skin hygiene and avoid maceration; do not put an interface (sheet, towel, etc.) between the complete seat (back and seat) which causes surface tension, to maintain the cushion's effectiveness,
 - o Once a day, observe the condition of the skin, or ensure that it is observed,
 - o In case of incontinence, change the protective cover regularly,
 - o Regularly drink enough fluids,

→ If any of these measures cannot be followed, it is essential to inform your doctor or nurse as soon as possible.

- For the support to be effective, it is important to keep excess thickness between the body and the support to a minimum (sheets, full nappy, etc.). Preferably wear loose-fitting cotton outerwear, if possible, without seams in the support area.
- Make sure there are no foreign bodies such as tubes, crumbs, grease, etc.
- Important: consult your prescriber within a month of purchasing the cushion.
- Reinforced surveillance in subjects at risk of falling (patient profile: invalid, agitated, not lucid).

PREVENTIVE MAINTENANCE





Regularly check the cover for holes or signs of erosion.
Contact your dealer in case of abnormal deterioration.


CARE AND DISINFECTION

CLEANING THE COVER






Surface cleaning and disinfection (bioneting). Compatible with steam processes.
Machine washable at a recommended temperature of 60°C with a cold-down principle. Open the zip.

The following conditions must be respected for PHARMATEX covers:

	Moderate wash up to 90°C.
	Possible bleaching, maximum allowable chlorine concentration of 5000 ppm.
	Trumble dry on low heat.
	Do not iron.

	Do not dry clean.
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The following conditions must be respected for 3D mesh and JERSEY covers:

	Moderate wash up to 40°C.
	Prohibited bleaching.
	Tumble dry on low heat.
	Do not iron.
	Do not dry clean.

CAUTION

Do not use corrosive cleaning products or industrial degreasers to avoid damage to the textile.

DISPOSAL

Do not burn or throw away the used product.

Take it to a waste disposal site, which will take care of it.



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